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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/308,295	05/17/99	CLARK	158105

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EXAMINER

BASI, N

ART UNIT

PAPER NUMBER

1546

DATE MAILED: 10/13/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/308,295

Applicant(s)

Clark Etal

Examiner

Nirmal. S. Basi

Group Art Unit

1646



☒ Responsive to communication(s) filed on Jul 22, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-5 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-5 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **DETAILED ACTION**

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1646.

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#### ***Specification***

1. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

#### ***Priority claimed***

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Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C.119(e) as follows: "The DECLARATION AND POWER OF ATTORNEY" does not claim priority to Application Serial No. 60/033,227. "The DECLARATION AND POWER OF ATTORNEY" must contain a statement that priority to Application Serial No. 60/033,227 is claimed under 35 U.S.C.119(e).

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Appropriate correction is required.

#### **Claim Rejection, 35 U.S.C. 112**

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4. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 is indefinite because it is not clear what is "aberrant alternate splice form of the human glucocorticoid receptor (GR $\beta$ )". Aberrant means deviating from normal. Therefore without reference to what form of the GR $\beta$  is considered normal the metes and bounds of the claim can not be determined. Further, without an indication of what is the structure of the GR gene it is not clear what would be the defects in said gene. The claim should refer to GR gene and GR $\beta$  by SEQ ID NO: identifier.

Claims 2 rejected due to the improper Markush grouping. The claim refers to a group containing both methods and non-methods. Further, the claim is indefinite because denaturing gradient gel and single-stranded conformation polymorphism (SSCP) are not methods.

Claims 3 and 4 are indefinite because it is not clear what are "genetic changes". The claims nor specification define "genetic changes" so as to allow the metes and bounds of the claim to be determined. Further claims 3 and 4 indefinite because it is not clear what is "altered GR $\beta$  expression". Alter means to make different. Therefore without reference to the unaltered structure of GR gene and unaltered structure of GR $\beta$  the metes and bounds of the claim can not be determined. Therefore, without an indication of the structure of the GR gene and GR $\beta$  it is not clear what would be the genetic changes or alterations in said gene. The claim should refer to GR gene and GR $\beta$  by SEQ ID NO: identifier. Further, claim 4 is indefinite because it is not clear what "changes outside" the GR gene are being referred to. The claims nor specification define "changes outside" so as to allow the metes and bounds of the claim to be determined.

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Claims 1 and 5 are indefinite because it is not clear what is implied by "GR $\beta$  expression". GR $\beta$  expression has not been defined in the claims or the specification so as to allow the metes and bounds of the claim to be determined.

Claims 1-4 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for  
5 omitting essential elements, such omission amounting to a gap between the elements. See MPEP  
§ 2172.01. The omitted elements are: the method steps to achieve the goal of the preamble.

Claims 1-4 are indefinite because the method steps do not achieve the goal of diagnosing for  
glaucoma as stated in the preamble. An acceptable method claim must contain three sections: 1)  
a preamble, 2) method steps that clearly define what is to be done in each step, and 3) a  
10 conclusion that what was stated in the preamble was achieved (the method does not contain an  
assay step which states how and when the goal of the claim is achieved). Further, for clarity the  
name "GR " should be replaced with glucocorticoid receptor.

Claim 5 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for  
omitting essential elements, such omission amounting to a gap between the elements. See MPEP  
15 § 2172.01. The omitted elements are: the method steps to achieve the goal of the preamble.

Claim is indefinite because the method steps do not achieve the goal of diagnosing for  
determining whether an agent is useful for treating glaucoma as stated in the preamble. An  
acceptable method claim must contain three sections: 1) a preamble, 2) method steps that clearly  
define what is to be done in each step, and 3) a conclusion that what was stated in the preamble

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was achieved (the method does not contain an assay step which states how and when the goal of the claim is achieved).

**Claim Rejection, 35 U.S.C. 112**

5 1. Claims 1-5 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-2 are drawn to a method of diagnosing glaucoma which comprises detecting aberrant alternate splice form of the GR $\beta$  or defects in a GR gene which encoded GR $\beta$ . The  
10 claims suggest possible general assays which may be used to achieve the goal of the preamble but the specification, claims or prior art do not state how to use said assays to specifically diagnose glaucoma and no indication of the arrangement of the method steps is given. Claims 3 and 4 are directed to methods for diagnosing glaucoma by detecting genetic changes in the GR gene, and outside the gene, leading to altered GR $\beta$  expression. Claims 3 and 4 do not disclose any assay  
15 or method steps which may be used to achieve the goal of the preamble and the specification, claims or prior art do not state how to specifically diagnose glaucoma by detecting genetic changes in the GR gene leading to altered GR gene GR $\beta$  expression. Claim 5 is directed to a method for determining whether an agent is useful for treating glaucoma by determining whether it interacts with GR $\beta$  or alters the expression of GR $\beta$  by detecting genetic changes in the GR  
20 gene, and outside the gene, which lead to altered GR $\beta$  expression. Claim 5 does not disclose

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any assay or method steps which may be used to achieve the goal of the preamble and the specification, claims or prior art do not state how to specifically determine if an agent that interacts with GR $\beta$  is useful for treating glaucoma. The specification does not provide the structure of GR $\beta$  or the GR gene, does not disclose what defects in the GR gene are indicative of the presence of glaucoma, what genetic changes in, and outside, the GR gene lead to altered GR $\beta$  expression and how these changes are indicative of the presence of glaucoma, and how an agent that interacts with GR $\beta$  or alters its expression is indicative of the presence of glaucoma.

Prior art and the specification discloses that various tissues express the both GR $\alpha$  and GR $\beta$ , and that the alternate splice form, GR $\beta$ , does not bind glucocorticoids. The specification states that"

Surprisingly, it has been found that cultured human trabecular meshwork cell lines derived from glaucomatous donors express mRNA for both an alternate splice form of the human glucocorticoid receptor (GR $\beta$ ), as well as the normal glucocorticoid receptor (GR $\alpha$ ). Further it is believed that elevated intraocular pressure associated with primary open-angle glaucoma may be due to the aberrant expression of GR $\beta$  in the tubular meshwork. Therefore, determining that an individual abnormally expresses GR $\beta$  in their trabecular meshwork or other tissues can lead to a diagnosis of glaucoma", see page 2, second paragraph. The disclosure nor prior art provides any experimental detail or data to support the above statement in the specification. Prior art nor the specification provide the mechanism of GR $\beta$  interaction with GR $\alpha$ , how this relates to their interaction with glucocorticoids and their involvement with the onset of glaucoma. Since various tissues can express both GR $\alpha$  and GR $\beta$  it is not clear what the nexus is between the expression

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of GR $\alpha$  and GR $\beta$  and glaucoma. Therefore, without evidence that detection of GR $\beta$  in tissue is indicative of a diagnosis for glaucoma, lack of assay steps in the method claims, the complex nature of the interactions in the disease state of glaucoma the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to  
5 make/use the invention commensurate in scope of claims 1-5.

No claim is allowed.

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**Advisory Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 308-0294.

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Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Nirmal S. Basi  
Art Unit 1646  
September 30, 2000

  
YVONNE EYLER, P.E.  
PRIMARY EXAMINER